UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
[illegible]	03/21/99	SOLOMON	A 04137-5025

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HM11/0118

EXAMINER
TURNER,S

ART UNIT	PAPER NUMBER
1647	10

DATE MAILED: 01/18/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/95)

U.S. G.P.O. 1999 460-693

1- File Copy

Office Action Summary

Application No.	Applicant(s)
09/316,387	Solomon et al.
Examiner	**Group Art Unit**
Sharon L. Turner, Ph.D.	1647

☒ Responsive to communication(s) filed on 10-30-00

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-22 is/are pending in the applicat

Of the above, claim(s) 10-22 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-9 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-22 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6, 9

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Applicant's election of Group I, claims 1-9 in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election **without** traverse (MPEP § 818.03(a)).

2. Claims 10-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 9 requires the essential material of monoclonal antibodies κ1(57-18H12), κ4(11-1F4), and λ8(31-8C7). However, the specification lacks complete deposit information for the recited antibodies. Because it is not clear that the antibodies possessing the properties of κ1(57-18H12), κ4(11-1F4), and λ8(31-8C7) are known and publicly available or can be reproducibly isolated from nature without undue experimentation and because the claims require the use of κ1(57-18H12), κ4(11-1F4), and λ8(31-8C7), a suitable deposit for patent purposes is required. Accordingly, filing of evidence of the reproducible production of the antibodies claimed in claim 9 is required. Without publicly available deposit of the above, one of ordinary skill in the art

could not be assured of the ability to practice the invention as claimed. Exact replication of the antibodies is an unpredictable event.

Applicant's referral to the deposit at p. 19 is an insufficient assurance that all required deposits have been made and all the conditions of 37 CFR § 1.801-1.809 have been met in particular as no deposit number is provided.

If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty and that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of the patent on this application. These requirements are necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of deposit and the complete name and full street address of the depository is required.

If the deposits have not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR § 1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

© the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material whichever is longest; and

(d) the deposits will be replaced if they should become nonviable or non replicable.

In addition, a deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the depository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of a biological material not made under the Budapest Treaty must be filed in the application and must contain:

1) The name and address of the depository;

2) The name and address of the depositor;

3) The date of deposit;
4) The identity of the deposit and the accession number given by the depository;
5) The date of the viability test;
6) The procedures used to obtain a sample if the test is not done by the depository; and
7) A statement that the deposit is capable of reproduction.

As a means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the κ1(57-18H12), κ4(11-1F4), and λ8(31-8C7) antibodies described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundack, 773F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR § 1.801-1.809 for further information concerning deposit practice.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites a "therapeutically effective dose" without defining the relevant amount or result to be obtained and thus the metes and bounds/scope of the claim cannot readily be discerned by one of skill in the art.

Claim Rejections - 35 USC § 102 or 103

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1, and 3-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Walker et al., J. of Neuropath. & Exp. Neurol., 53(4):377-83, July 1994.

Walker et al., teach administration of monoclonal antibody 10D5 to living nonhuman primates. 10D5 specifically bound amyloid deposits in cerebral cortex and thus the method comprises treating a patient having an amyloid deposition disease by administration of an immunoglobulin polypeptide which binds to an amyloid fibril, see in particular abstract. The injection was provided in sterile saline, a pharmaceutically acceptable carrier, see in particular p.

378, column 1, Injection of antibody, lines 1-2. The antibody inherently opsonizes upon binding, absent evidence to the contrary. Thus, the reference teachings anticipate the claimed invention.

10. Claims 1, 3-4 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Konig et al., WO96/25435, 22 August 1996.

Konig et al., teach administration of monoclonal antibodies which bind amyloid fibrils, see in particular claims 9-20 and pp. 6-8 for treatment of Alzheimers disease. The antibodies specifically bind amyloid fibrils, see in particular p. 6, line 25. Thus, the reference teaches a method which comprises treating a patient having an amyloid deposition disease by administration of an immunoglobulin polypeptide which binds to an amyloid fibril. The antibodies can be provided in sterile saline or a pharmaceutically acceptable carrier such as Keyhole Limpet Hemocyanin, see in particular p. 17. The antibody inherently opsonizes upon binding, absent evidence to the contrary. The antibodies may be labeled by biotinylation or with radioactive tags such as 35S-Met, see in particular p.22. Thus, the reference teachings anticipate the claimed invention.

11. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wrightham et al., Blood, 69(3):919-23, March 1987, Walker et al., J. of Neuropathol. & Exp. Neurol., 53(4):377-83, July 1994 (set forth above), Konig et al., WO96/25435, 22 August 1996 and applicants specification.

Walker et al., as set forth above teach in vivo administration of monoclonal antibody specific to labeling amyloid fibrils.

Wrightham et al., teach monoclonal anti-light chain antibodies which specifically detect idiotypic lambda chain but not normal lambda chains and reacted with idiotypic IgM from tumor cells. The authors teach that such antibodies to idiotypic determinants on light chains show technical advantages and should be useful for monitoring and possibly treating B cell tumors.

Konig et al., as set forth above, teach methods of diagnosis, screening and therapeutics for treating unique forms of amyloid peptide deposition using antibodies.

Applicants specification at pp. 14-16 teach the routine of one of skill in the art to produce humanized and chimeric antibodies.

Thus, it would have been prima facie obvious to the skilled artisan to utilize the Wrightham et al., antibody for in vivo administration as taught by Walker et al. and Konig et al., to specifically bind, visualize and treat the B cell tumors. One of skill in the art would have expected success based upon the combined teachings and success of Walker, Wrightham and Konig.

In addition, as set forth in the specification, one of skill in the art routinely performs humanization or the production of chimeric antibodies for use in alternate species. Thus, one of skill in the art would be motivated to treat alternative individuals by humanizing or producing chimeric antibodies to the defined anti-light chain immunogen as defined by Wrightham. One would expect success based on the high skill in the art. Thus, for the aforementioned reasons, the claimed invention is rendered obvious to the skilled artisan.

Status of Claims

12. **No claims are allowed.**

13. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.
January 15, 2001

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud